



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 30 2004

Mr. Robert Eusebio
Manager Regulatory Affairs
Dade MicroScan, Inc.
1584 Enterprise Boulevard
West Sacramento, CA 95691

Re: k020319

Trade/Device Name: MicroScan® Synergies plus™ Gram-Negative MIC/Combo Panels
with Ampicillin/Sulbactam (0.5/0.25- 64/34 µg/ml)

Regulation Number: 21 CFR 866.1645

Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial
Susceptibility Devices

Regulatory Class: Class II

Product Code: LON

Dated: July 30, 2004

Received: August 3, 2004

Dear Mr. Eusebio:

This letter corrects our substantially equivalent letter of April 17, 2002, regarding the trade name which was changed to MicroScan® Synergies Plus to better reflect the intended use of the device.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-3084. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K020319

Device Name: MicroScan® Synergies plus™ Gram-Negative MIC/Combo Panels with Ampicillin/Sulbactam (0.5/0.25 – 64/32 µg/ml)

Indications For Use:

MicroScan® Synergies plus™ Gram-Negative MIC/Combo Panel is used to determine quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic Gram-Negative bacilli (Enterobacteriaceae, glucose non-fermenters, and non-Enterobacteriaceae glucose fermenters. After inoculation, panels are read on the WalkAway® SI System or equivalent (upgraded WalkAway® 40 or WalkAway® 96) according to the Package Insert.

This particular submission is for the antimicrobial Ampicillin/Sulbactam on the Synergies plus™ Gram-Negative MIC/Combo Panels.

The Gram-Negative organisms which may be used for Ampicillin/Sulbactam susceptibility testing in this panel are:

Escherichia coli
Klebsiella spp.
Proteus mirabilis
Proteus vulgaris
Providencia rettgeri
Providencia stuartii

The MicroScan® Synergies plus™ Gram-Negative with Ampicillin/Sulbactam is not intended for use with:

Acinetobacter calcoaceticus
Citrobacter spp.
Enterobacter spp.
Morganella morganii
Salmonella spp.
Shigella spp.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 020319

510(k) Summary

510(k) Submission Information:

Device Manufacturer: Dade Behring Inc.
 Contact name: Maureen Mende, Group Manager Regulatory Affairs
 Fax: 916-374-3144
 Date prepared: April 15, 2002
 Product Name: Microdilution Minimum Inhibitory Concentration (MIC) Panels
 Trade Name: MicroScan® rapID/S *plus*™ Gram-Negative MIC/Combo panels
 Intended Use: To determine antimicrobial agent susceptibility
 510(k) Notification: Antimicrobials: Ampicillin/Sulbactam
 Predicate device: MicroScan Dried Gram Negative MIC/Combo Panels

510(k) Summary:

MicroScan® rapID/S *plus*™ Gram-Negative MIC/Combo Panels are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic gram-negative bacilli. The MicroScan® rapID/S *plus*™ Gram-Negative MIC/Combo Panels are read on the WalkAway® SI System or equivalent (upgraded WalkAway® 40 or WalkAway® 96 instruments).

The antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test that have been diluted in Mueller-Hinton Broth to concentrations bridging the range of clinical interest and are presented in micro-titer wells in dried form. rapID/S *plus*™ panels are inoculated and rehydrated with a standardized suspension of the organism and incubated at 35°C in the WalkAway® SI System or equivalent for 4.5 – 18 hours. The minimum inhibitory concentration (MIC) for the test organism is determined by the lowest antimicrobial concentration showing inhibition of growth.

The proposed MicroScan® rapID/S *plus*™ Gram-Negative MIC/Combo Panel demonstrated substantially equivalent performance when compared with an NCCLS frozen Reference Panel, as defined in the FDA DRAFT document "Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices", dated March 8, 2000. The Premarket Notification (510[k]) presents data in support of the MicroScan® rapID/S *plus*™ Gram-Negative MIC/Combo Panel with Ampicillin/Sulbactam.

The external evaluation was conducted with fresh and stock Efficacy isolates and stock Challenge strains. The external evaluations were designed to confirm the acceptability of the proposed rapID/S *plus*™ Gram-Negative Panel by comparing its performance with an NCCLS frozen Reference panel. Challenge strains were compared to Expected Results determined prior to the evaluation. The rapID/S *plus*™ Gram-Negative Panel demonstrated acceptable performance with an overall Essential Agreement of 92.5% for Ampicillin/Sulbactam when compared with the frozen Reference panel.

Instrument reproducibility testing demonstrated acceptable reproducibility and precision with Ampicillin/Sulbactam with Turbidity inoculum preparation method and the WalkAway® SI System or equivalent (upgraded WalkAway® 40 or WalkAway® 96 instruments).

Quality Control testing demonstrated acceptable results for Ampicillin/Sulbactam.